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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,597	10/30/2003	Ruxandra Draghia-Akli	AVSI-0027 (108328.00161)	7762
70225	7590	07/14/2009	EXAMINER	
JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	
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			07/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1633

DETAILED ACTION

This office action is in response to an amendment filed 3/31/09. Claims 29-31, 39 and 42 are pending in this office action.

Election/Restrictions

Until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. If the product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. At this time, the product claim has not been found allowable.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, pages figures 12-19 each comprise two sequences that are not identified by SEQ ID NO:.. If the sequences can be found in the sequence listing it would be remedial to insert the appropriate SEQ ID NO:s. If not, a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, CRF and letter stating that the contents of the sequence listing and the CRF are the same and contain no new matter is required. **The**

Art Unit: 1633

nature of the non-compliance did not preclude the examination on the merits of the instant application, the results of which follow.

Response to Amendment

Applicants have amended the description of drawings to insert a single SEQ ID NO: to describe each of the figures. However, there are two sequences in each figure that are not the same as one another. Therefore, a second SEQ ID NO: is required for each figure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This

Claims 39 is drawn to a cardiac specific-synthetic promoter comprising:

(a) a synthetic promoter element comprising c5-12 (SeqID#5) and further comprising at least one (b) cis-acting regulatory element comprising SRE (SeqID#1); MEF-1 (SeqID#2); MEF-2 (SeqID#3); or TEF-1 (SeqID#4). SEQ ID NO:5 which comprises all of cis-acting regulatory

Art Unit: 1633

element comprising SRE (SeqID#1); MEF-1 (SeqID#2); MEF-2 (SeqID#3); and TEF-1 (SeqID#4) as set forth below.

While c5-12 is set forth as

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c5-12
          SRE-1  TEF-1
ggaggtcaggc attcggtccc atcccccga caccacaaa tggcgttgc tggggatcgc 50
          MEF-2  MEF-1  MEF-3
ctggggctca tttttagggc gttcgagggc gggggcgagc scgagtgatt ggggtcttgg 120
          MEF-2  SRE-2
cactactcc cggagctat ttttagggc gaggatggc gacacccca ataggggag 180
          SRE
ggttctctcc ccttcgcat atttgatgt gggccctgg cgggggcgc attctgggg 240
ggcgggtggg gctcgggccc gcttcgggaa aggggtctgg ggcggggggc gggccacggg 300
ctacggggag gggcggggag cggcggctc taga 334

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Hence, claim 39 as recited is drawn to a modification of SEQ ID NO:5 in which additional elements are added. But the specification does not disclose such a promoter. Hence, claim 39 is not supported by the disclosure and constitutes impermissible NEW MATTER.

Response to Amendment

Applicants response filed 3/31/09 has been considered but is ineffective in overcoming the rejection under 35 USC 112, first paragraph. Applicants arguments appear directed at a claim drawn to SEQ ID NO:5 wherein SEQ ID NO:5 comprises at least one of SEQ ID NO:s 1-4. However, the claim is drawn to SEQ ID NO:5 *further* comprising at least one of SEQ ID

Art Unit: 1633

NO:s 1-4. The specification teaches that c5-12 is SEQ ID NO:5. The specification does not teach modifications of this sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al (US 5,298,422; see entire document). **This is a new rejection necessitated by applicants' amendment. The instant claim recites that the promoter has "a" sequence as set forth in SEQ ID NO:5. This rejection is directed towards a reading of the claims of a single dinucleotide from SEQ ID NO:5.**

Schwartz et al teach a myogenic vector for expression of a sequence in myogenic tissue (cardiac tissue) using a cardiac specific synthetic promoter (see e.g. figure 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Draghia-Akli et

Art Unit: 1633

al (US 7,241,744; see entire document). **This is a new rejection necessitated by applicants' amendment. This rejection is directed towards a reading of the claims of the sequence of SEQ ID NO:5. The rejection has been clarified to reflect that the sequence shown below is SEQ ID NO:16.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants claim a cardiac specific promoter comprising SEQ ID NO:5.

Draghia-Akli et al teach a promoter (SEQ ID NO:16) and furthermore this promoter is 99.7% identical to SEQ ID NO:5. The difference between the two is the first nucleotide which is missing from 10/315907. However, according to the diagram of SEQ ID NO:5, this nucleotide does not perform a critical function nor does it function in the capacity of the promoter. KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Exparte Smith --USPD2d--*, slip op. at 20, (BD. Pat. App. & Interfer. June 25, 2007). As well, it is within the ordinary skill of the art to use available methodologies to isolate a variety of promoters with C-terminal or N-terminal sequences removed that do not affect the function of the promoter. One would have been motivated to do so in order as the ability to modify sequences by applying conventional

Art Unit: 1633

methodologies. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

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      RESULT 1
US-10-315-907C-16
; Sequence 16, Application US/10315907C
; Patent No. 7241744
; GENERAL INFORMATION:
; APPLICANT: Advisys
; TITLE OF INVENTION: PLASMID MEDIATED SUPPLEMENTATION FOR TREATING
CHRONICALLY ILL SUBJECTS
; FILE REFERENCE: 108328.00073 - AVSI-0007
; CURRENT APPLICATION NUMBER: US/10/315,907C
; CURRENT FILING DATE: 2002-12-10
; NUMBER OF SEQ ID NOS: 25
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 16
; LENGTH: 4260
; TYPE: DNA
; ORGANISM: Artificial sequence
; FEATURE:
; OTHER INFORMATION: Sequence for the pSP-SEAP cDNA construct
; Patent No. 7241744
US-10-315-907C-16

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Query Match          99.7%; Score 334; DB 5; Length 4260;
Best Local Similarity 100.0%; Pred. No. 1.8e-83;
Matches 334; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

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Qy          2 GGCCGTCCGCCTTCGGCACCATCCTCACGACACCCAAATATGGCGACGGGTGAGGAATGG 61
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 GGCCGTCCGCCTTCGGCACCATCCTCACGACACCCAAATATGGCGACGGGTGAGGAATGG 60

Qy          62 TGGGGAGTTATTTTTAGAGCGGTGAGGAAGGTGGGCAGGCAGCAGGTGTTGGCGCTCTAA
121
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          61 TGGGGAGTTATTTTTAGAGCGGTGAGGAAGGTGGGCAGGCAGCAGGTGTTGGCGCTCTAA
120

Qy          122 AAATAACTCCCGGGAGTTATTTTTAGAGCGGAGGAATGGTGGACACCCAAATATGGCGAC
181
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          121 AAATAACTCCCGGGAGTTATTTTTAGAGCGGAGGAATGGTGGACACCCAAATATGGCGAC
180

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Art Unit: 1633

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Qy      182  GGTTCTCACCCGTCGCCATATTTGGGTGTCCGCCCTCGGCCGGGGCCGCATTCTGGGG
241      |
Db      181  GGTTCTCACCCGTCGCCATATTTGGGTGTCCGCCCTCGGCCGGGGCCGCATTCTGGGG
240      |

Qy      242  GCCGGGCGGTGCTCCCGCCCGCCTCGATAAAAGGCTCCGGGGCCGGCGGCGGCCACGAG
301      |
Db      241  GCCGGGCGGTGCTCCCGCCCGCCTCGATAAAAGGCTCCGGGGCCGGCGGCGGCCACGAG
300      |

Qy      302  CTACCCGGAGGAGCGGGAGGCGCCAAGCTCTAGA  335
Db      301  CTACCCGGAGGAGCGGGAGGCGCCAAGCTCTAGA  334

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Response to Amendment

Applicants response filed 3/31/09 has been considered but is ineffective in overcoming the rejection under 35 USC 102 and 103. Applicants have argued that neither SEQ ID NO:1 nor 7 of Draghia-Akli et al matches that of SEQ ID NO:5. However, as set forth in the body of the rejection, a match of 99.7% of SEQ ID NO:16 and SEQ IDNO:5 have been identified. While the sequences was incorrectly listed in the body of the rejection as SEQ ID NO:1, it was correctly set forth in the sequence comparison. This sequence number identifier is bolded in the computer generated sequence alignment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1633

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

Application/Control Number: 10/699,597

Page 10

Art Unit: 1633

/Maria B Marvich,/

Primary Examiner, Art Unit 1633